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SUMMARY OF SAFETY AND EFFECTIVENESS

General Company Information

Name: Alveolus Inc.

Address: 401 North Tryon Street, 10th Floor
Charlotte, NC 28202

Telephone: (704) 998 - 5300
Fax: (704) 998 - 5301

General Device Information

Product Name: TB-STS™ Tracheobronchial Stent System

Classification: "Tracheal Prosthesis", Product code: JCT
Class II

Predicate Devices

Alveolus, Inc. TB-STS™ Tracheobronchial Stent System
[510(k) Number K030947]

Boston Scientific Corp. Inc. Ultraflex™ Tracheobronchial Stent System
[510(k) Number K963241]

Vascular Architects, Inc. aSpire™ Covered Stent and CONTROLLED EXPANSION ™ Delivery System [510(k) Number K003173 and K012544]

Description

The Alveolus tracheobronchial stent technology system is comprised of two components: the radiopaque stent and the delivery system. The nitinol stent is completely covered with a biocompatible polyurethane (ChronoFlex™) membrane and is self-expanding. The inner lumen of the expanded stent is coated with a hydrophilic polymer to improve lubricity. The stent expansion results from the mechanical properties of the metal and the proprietary geometry. The stent is designed with a slightly larger diameter near the distal and proximal ends to minimize the possibility of migration. The stent ends are slightly vaulted inwardly in order to minimize possible airway injury from the stent edges. The overall stent geometry is designed to maintain a constant length over the entire range of possible diameters. As a result of this unique design the stent has virtually no foreshortening, thus facilitating the selection of the appropriate stent length.

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Indications

The Alveolus TB-STS™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures and airway compression (stenosis) produced by malignant neoplasms. Because the device is removable it may also be used to treat benign conditions such as tracheo-esophageal fistulae and strictures resulting from surgical anastomosis of the airway.

Substantial Equivalence

This submission supports the position that the modified Alveolus Tracheobronchial Stent is substantially equivalent to a number of previously cleared devices, including the Alveolus TB-STS™ Tracheobronchial Stent System previously approved [510(k) K030947], the Boston Scientific Corp. Inc. Ultraflex™ Tracheobronchial Stent System [501(k) Number K963241] and the Vascular Architects, Inc. aSpire® Covered Stent® [510(k) Numbers K003173 and K012544].

The 510(k) Notice contains summaries of physical test results, and biocompatibility test results as specified in the FDA Guidance Document for Testing Esophageal and Tracheal Prostheses (April 28, 1998).

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use.

The single-patient-use components of the TB-STS™ Tracheobronchial Stent System are provided sterile.

Alveolus Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical application as the Alveolus Tracheobronchial Stent. The materials from which the Alveolus device is fabricated have an established history of use in clinical applications, and the devices produced by Alveolus have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2 2004

Mr. Howard L. Schrayer
Alveolus, Inc.
401 N. Tryon Street, 10th Floor
Charlotte, North Carolina 28202

Re: K033990
Trade/Device Name: Alveolus, TB-STS™ Tracheobronchial Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: April 9, 2004
Received: April 12, 2004

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033990

Device Name: Alveolus, TB-STS™ Tracheobronchial Stent System

Indications For Use:

The Alveolus TB-STS™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures and airway compression (stenosis) produced by malignant neoplasms. Because the device is removable it may also be used to treat benign conditions such as tracheo-esophageal fistulae and strictures resulting from surgical anastomosis of the airway.

Prescription Use ✓ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033990